

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status Of The Claims

Claims 84-92 are pending. Claims 1-83 were previously canceled without prejudice or disclaimer. Claims 84-86, 88 and 89 are amended. Support for the amendments can be found throughout the specification, for example, at page 15, lines 4-22, and at page 30, lines 4-20. No new matter has been added.

II. Objection To The Claims

Claims 84-92 were objected to as containing non-elected subject matter. Office action, page 5. Applicants have obviated this objection by amendment. The claims as amended recite compounds of formula IV corresponding to Group IV of the Restriction Requirement of March 8, 2004. Accordingly, applicants respectfully request withdrawal of this ground of objection.

III. 35 U.S.C. § 112, First Paragraph

Claims 88-92 were rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably provide enablement for effecting a neuronal activity or treating all neurological disorders. Office action, page 2. The PTO reasoned the specification does not enable any person skilled in the art to use the invention commensurate in scope with the claims. Office action, page 2. The PTO concluded that the specification is not enabling based on at least four of the *Wand* factors, *i.e.* quantity of experimentation necessary, the amount of direction or guidance provided, the presence of working examples, and the state of the prior art and the breadth of the claims. Office action, pages 2-3.

Based on the specification and working examples, the PTO acknowledged the instant compounds will have utility in treating Parkinson's Disease. Office action, page 3. In contrast, the PTO concluded there is no teaching in the specification or prior art that

promotion of neurite outgrowth in vitro using chick sensory neurons represents a valid model for efficacy of the in vivo activity for effecting neuronal activity in general. Office action, page 3. The PTO also reasons that there is no teaching that the etiology of all known neurological disorders and neurodegenerative disorders are the same. Office action, page 3. The PTO also noted that the specification lacks working examples showing the efficacy of the instant compounds in known animal models of all neurological disorders and all known neurodegenerative disorders. Office action, page 4. Lastly, the PTO reasoned that, due to the thousands of possible compounds, it would require undue experimentation to demonstrate the efficacy of the instant compounds in known animal models of neurological and neurodegenerative disorders. Office action, page 4.

First, it is well known in the art that in vitro outgrowth of chick sensory neurons represents a valid model for the in vivo efficacy of compounds. *See* MPEP § 2164.02. This model was used for example by Wilson et al., *J. Cell Sci.* 109:3129-3138 (1996), to test compounds which inhibit neurite outgrowth; by Williamson et al., *J. Biol. Chem.* 271(6):31215-31221 (1996), to test compounds in a model for Alzheimer's Disease; by Lee K.D. and P.J. Hollenbeck, *J. Biol. Chem.* 270(10):5600-5605 (1995), to test the phosphoisoforms of cellular kinesin during neurite outgrowth; by Meyer S.U. and S. Henke-Fahle, *Proc. Natl. Acad. Sci. U.S.A.* 92(24):11150-11154 (1995), where the author's stated that their "findings show the chick central nervous system to be a suitable model for studying the function of extracellular molecules in vivo" (page 11154, col 2)); and by Neugebauer et al., *J. Cell Biol.* 107(3):1177-87 (1988), to identify molecules that may mediate axon extension in vivo.

Moreover, the in vitro outgrowth of other models, and their correlation to in vivo activity, were well known in the art. For example, in vitro models utilizing rat neurons can be found in Steiner et al., *Proc. Natl. Acad. Sci. U.S.A.* 94(5):2019-20124 (1997), and Kinnunen et al., *J. Biol. Chem.* 271(4):2243-2248 (1996). Although an exact correlation is not required, it is apparent from these reports that the in vitro outgrowth of chick sensory neurons, among other models, was recognized by those skilled in the art as correlating to in vivo neuronal

activity of compounds. *See* MPEP § 2164.02. Accordingly, those skilled in the art would expect, based on the state of the art, to be able to extrapolate the in vitro outgrowth of chick sensory neurons across the scope of the present claims. *See* MPEP § 2164.02.

Additionally, the methods of the claimed invention encompass the “stimulation of damaged neurons, promotion of neuronal regeneration, or treatment of a neurological disorder.” Here, the evidence and explanation of record does not make clear why those skilled in the art would be concerned with the etiology, or cause, of a specific neurological disorder when the claimed invention is used to ameliorate the effects of the disorders.

Lastly, the claimed compounds do not require undue experimentation to demonstrate their efficacy. As demonstrated above, those skilled in the art would have been aware of several in vitro and in vivo models of neural activity, including the model taught by the application. As presently claimed, the inventive compounds are a limited class and are structurally related to the compounds taught in the application to effect neurite outgrowth. As such, the application gives those skilled in the art sufficient guidance or direction in which experimentation should proceed. *See* MPEP §2164.06.

In view of the above, applicants respectfully request the withdrawal of this ground of rejection.

IV. 35 U.S.C. § 112, Second Paragraph

In the Office action, claims 88 and 89 were rejected under 35 U.S.C. § 112, second paragraph. Pages 4-5. Claim 89 was rejected as indefinite for reciting the term “prevention.” Office action, page 5. This rejection was obviated by amendment. Claims 88 and 89 were rejected as indefinite for reciting the term, “effecting.” Office action, page 4. In the Office action, the PTO concluded the term “effecting” in claims 88 and 89 was indefinite, under 35 U.S.C. § 112, second paragraph, as it was not clear how and where the neuronal activity is being effected. *See* Office action, page 4-5. Applicants traverse the rejection for reciting the term “effecting.”

Applicants are surprised to face this rejection because the Examiner has allowed claims with the same term used in the same context in U.S. Patent Nos. 5,786,378, 5,990,131, and 6,417,209. The PTO's interpretation of claim terms should be consistent and should not conflict with the meaning given to identical terms in other patents. *See In re Cortright*, 165 F.3d 1353, 1357 (Fed. Cir. 1999)

Further, Applicants' claims as written are definite, as the plain meaning of "effecting" would be readily understood by a person of ordinary skill in the art to include at least all items listed in the office action. *See* page 4, last para. The scope is perhaps broad.

However, a broad claim is not indefinite for the purposes of 35 U.S.C. § 112, second paragraph, as long as the boundaries of the claim are capable of being understood. *See In re Gardner*, 427 F.2d 786, 788, 166 USPQ 138, 140 (CCPA 1970). As long as the scope of the claim, when read in light of the specification, is clear to one of ordinary skill in the art, the definiteness requirement has been met. *See, e.g., Slimfold Mfg. Co. v. Kinkead Indus.*, 810 F.2d 1113, 1116-17, 1 USPQ2d 1563, 1566-67 (Fed. Cir. 1987). Consequently, a broad claim that employs well-known language conventionally used in the art should not be objectionable under 35 U.S.C. § 112, second paragraph. *See, e.g., In re Miller*, 441 F.2d 689, 692-93, 169 USPQ 597, 599 (CCPA 1971); *In re Kamal*, 398 F.2d 867, 870, 158 USPQ 320, 322 (CCPA 1968). Such is the case here.

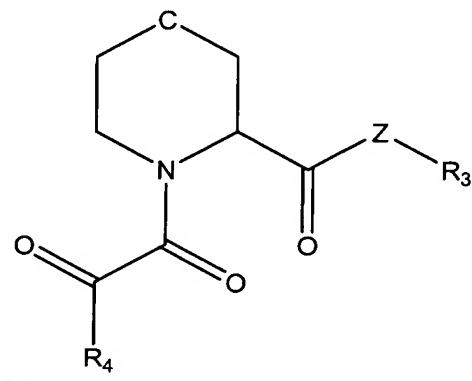
Accordingly, the term "effecting" is definite, and withdrawal of this ground for rejection is respectfully requested.

V. Obviousness-Type Double Patenting Rejection

Claims 84-92 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,486,151 ("the '151 patent"). Office action, page 5. Applicants respectfully traverse this ground of rejection.

The claimed compounds of the present application are patentably distinct over the claimed compounds of the '151 patent. *See* MPEP § 804. In this case, at issue is whether the

invention defined in a claim in the present application is an obvious variation of the claimed invention of the '151 patent. *See* MPEP § 804.II.B.1.(a). The '151 patent claims are all drawn to N-oxides. In contrast, the present claims as amended exclude N-oxides. Each independent claim now recites N-glyoxyl heterocyclic compounds of the following formula:



wherein C is S;
Z is CH₂ or S;
R₃ is 2-phenylpropyl or 3-phenylpropyl; and
R₄ is 1,1-Dimethylpropyl,.

The present claims are patentably distinct from claims 1-7 of the '151 patent. Accordingly, applicants respectfully request withdrawal of this ground of rejection.

VI. Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a

check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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